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(71) Applicant *(for all designated States except US)*: BETH ISRAEL DEACONESS MEDICAL CENTER [US/US]; 330 Brookline Avenue, Boston, MA 02215 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: COHN, William [US/US]; 104 Lagrange Street, Chestnut Hill, MA 02167 (US).

(74) Agents: HOOVER, Thomas, O. et al.; Hamilton, Brook, Smith & Reynolds, P.C., Two Militia Drive, Lexington, MA 02173 (US).

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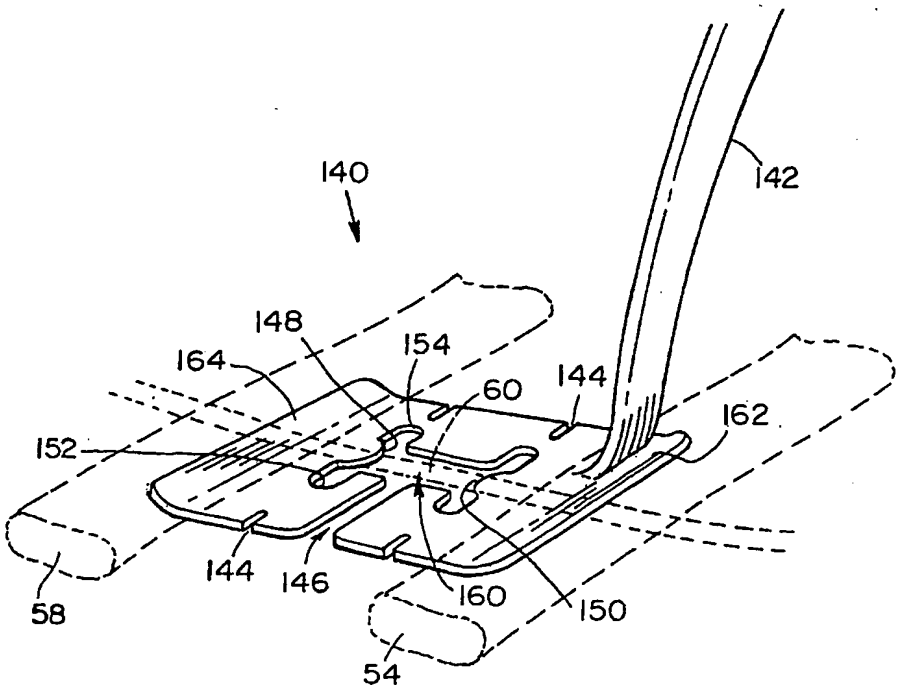

(57) Abstract

The present invention relates to a surgical retractor that immobilizes tissue at a surgical site. A preferred embodiment of the retractor is used during minimally invasive direct coronary bypass procedures to arrest movement of the grafting site while the heart continues pumping. Tape or thread can be used to connect the artery to the retractor with a holder.

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SURGICAL RETRACTOR

RELATED APPLICATIONS

This is a continuation-in-part application of U.S. Serial No. 08/845,333 filed on April 25, 1997, the entire contents of which is incorporated herein by reference.

BACKGROUND

Numerous devices have been used to position tissue at a surgical site to aid in the performing of surgical procedures. Retractors, for example, have been used to hold an artery in position during operations adjacent to the heart to prevent movement of the artery. This serves to minimize the risk of injury to the artery and adjacent tissue and can facilitate the desired anastomosis.

A recently developed procedure, referred to as the minimally invasive direct coronary artery bypass procedure, has been used to graft onto a coronary artery without cardiopulmonary bypass. This procedure involves the grafting of the left internal mammary artery (LIMA) onto the left anterior descending (LAD) or other artery. As this procedure does not require the use of a heart lung machine to oxygenate and pump blood, the morbidity and mortality associated with this procedure is substantially

lower than previous bypass techniques. A problem associated with the minimally invasive procedure, however, is that while the heart continues to pump during the procedure, the motion of the heart can interfere with the surgeon's task of attaching the LIMA to the LAD. There is also a need to stop blood flow in the area of the graft to maintain a clear field of view and provide precise suture placement.

Two basic strategies have been employed to address the problem of operating on a moving site, one being the use of pharmacological agents to limit heart motion, and the other being mechanical, such as a two prong retractor that is pushed down against the heart on both sides of the artery, or alternatively, upward traction away from the moving heart by traction tape or suture thread. Both of these options, however, have problems associated with them. Both options are susceptible to some movement of the vessel grafting site. The use of pharmacological agents is undesirable and impairs circulatory function. Traction by compression of the heart against the spine does serve to immobilize the site but can compromise the ability of the heart to maintain circulation and result in hypotension. Upward traction can involve circumferential compression of the artery to occlude the artery and prevent blood flow, however upward traction that is sufficient to immobilize the site can cause injury, stenosis or occlusion of the vessel.

There is a continuing need however for improvement in devices and methods for retaining tissue at surgical sites to further reduce the risks associated with surgical

procedures where the devices and methods are inexpensive, safe and reliable.

SUMMARY

The present invention relates to a surgical retractor for immobilizing tissue at a surgical site and to a method of using the retractor during a surgical procedure. A preferred embodiment of the retractor includes a retaining element having an aperture that exposes the surgical site and a holder that is used to position tissue at the surgical site relative to the retaining element. A handle can be attached to or fabricated with the retaining element or platform so that the user can manipulate the position of the retractor as needed.

In a preferred embodiment of the invention a connector such as elastic tape or thread is used to position tissue at the surgical site within the retractor aperture and to prevent movement of the tissue during the procedure. The connecting cord, thread or tape also aids in the compression of the artery in a grafting procedure to occlude flow on one or both sides of the surgical site. The cord is attached to the holder on the retaining element. A preferred embodiment of the holder can be a plurality of slits or openings positioned on both sides of the retractor that receive and frictionally secure the cord on both sides of the aperture. In another preferred embodiment a mechanical fastener is used to grip both sides of the cord. The fastener can be a spring mounted valve, for example, that allows the user to adjust the tension in

the cord.

A preferred embodiment of the invention comprises a retaining element or base having two sections that can be separated after the procedure is complete to permit removal of the retractor from under the grafted artery. Another preferred embodiment uses a side opening in the platform of the retractor that extends to the aperture so that the grafted artery slips through the side opening during removal. During minimally invasive direct coronary artery bypass operations, one or more surface sections of the retractor platform can be positioned against the inner surface or posterior aspect of one or both ribs adjacent to the surgical site. Thus, the size and geometry of the platform are selected to utilize the adjoining ribs where the upper surface of the platform frictionally engages the inner surface one or more ribs to hold the retractor in a fixed position. The retractor can be beneficial in any procedure where it is necessary to stabilize a surgical site. For example, the retractor can also be used for grafting onto the diagonal, right or other coronary arteries without altering the heart's pumping function.

The coronary arteries are about 1-2mm in diameter, and the pumping heart can move these arteries over distances of several millimeters during each heartbeat. As the movement of even 1 or 2 millimeters can result in a displacement of the grafting site that can substantially interfere with effective anastomosis, it is desirable to restrain movement of the artery at the surgical site in any direction to less than 1mm. The retractor of the present invention restrains

movement in the plane of the base to less than 0.5 mm, and preferably less than 0.2 mm.

In a preferred embodiment of the invention, the handle or articulating arm that is secured to the platform can be held in position by the user, attached to a frame that is fixed around the operative site or simply clipped to a drape around the site.

When used in a minimally invasive coronary bypass procedure, the retractor is positioned to expose the left anterior descending (LAD) artery grafting site after incision, removal of the rib section and dissection of the left internal mammary artery (LIMA) from the chest wall. A pair of cords, for example, sialastic tape (i.e. a silicon elastomer) or suture thread, are passed through the myocardium at two locations flanking the artery grafting site with blunt needles. The four ends of the two cords are connected to the platform holder with sufficient tension to occlude blood flow on both sides of the operative site. The tapes compress the artery against the bottom surface of the platform while they hold the artery grafting site in a fixed position relative to the aperture. The coronary artery is opened longitudinally and the end of the mammary artery is sewn to the graft opening with multiple fine sutures. The cords are released, blood flow is restored and the anastomosis is inspected for hemostatis and other defects and the wound is closed.

The platform can include tabs or cord retainers that extend into the aperture to provide a surface against which the arteries can be compressed.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a surgical retractor in accordance with a preferred embodiment of the invention.

Figure 2 is a perspective view of a surgical site illustrating a surgical procedure.

Figure 3 is a perspective view of a surgical retractor for a grafting procedure in accordance with the invention.

Figure 4 is a bottom perspective view of a surgical retractor in accordance with the invention.

Figure 5 is a cross-sectional view of a surgical retractor during a surgical procedure.

Figures 6A and 6B are partial cross-sectional views of a holder in accordance with the invention.

Figure 7 is a top view of a two piece retainer in accordance with the invention.

Figure 8 is a top perspective view of another preferred embodiment of a surgical retractor in accordance with the invention.

Figure 9 is a top perspective view of another preferred embodiment of a surgical retractor in accordance with the invention.

Figure 10 is a schematic diagram illustrating a surgical procedure in accordance with the invention.

Figure 11 is a perspective view of a frame supporting a retractor in accordance with the invention.

Figure 12A and 12B are enlarged detailed views of a surgical retractor in accordance with the invention.

DETAILED DESCRIPTION

A preferred embodiment of the invention is illustrated in connection with Figure 1. A retractor 10 includes a retaining element or base 12 having an aperture 16 that is positioned to expose tissue at a surgical site. The base 12 can be made with a metal or a molded plastic material. The retractor 10 can be sterilized after each use, or alternatively, can be disposable after one procedure. A handle 30 or articulating arm can be permanently attached to the base 12, or as described below in connection with other preferred embodiments, can be detachable.

A suction tube 32 can be attached to the handle 30 or integrated therein and is used to remove material such as blood from the operative site. In this particular embodiment the tube 32 is connected at one end to a tube 34 from a suction pump and connected at a second end to a port 36 in fluid communication with a channel within tube 28 that extends around the periphery of base 12. The peripheral tube can have small openings 38 positioned on the sides or top thereof through which fluid such as blood or other debris can be suctioned from the surgical site to maintain a clear field.

A preferred embodiment of the invention can be used at a surgical site 50 such as the example illustrated in Figure 2. In this particular procedure for a coronary graft without cardiopulmonary bypass, a section of the 4th costal cartilage or rib 56 is removed to expose a section of the LAD artery 61.

A proximal portion of the LIMA 62 is dissected from

the chest wall to expose an end 65 to be grafted onto a grafting site 60 on artery 61. Blood flow in vessel 62 can be occluded with a clamp 64.

In this example, a connector such as a pair of cords or sialastic tapes 70, 72 are threaded through myocardium surface 78 under the artery 61 at two locations 74, 76 on opposite sides of the grafting site 60. Note that the exposed surface 78 of heart 52 is undergoing substantial movement during the procedure.

As seen in the reverse perspective view of Figure 3 in which the retractor 10 has been inserted and positioned during the procedure, the retractor 10 serves to immobilize the grafting site 60 using connecting tapes 70, 72 which are stretched and attached to a holder mechanism including slots 20a-20d in the peripheral edge of base 12. As described in greater detail below, the slots 20A-20d can be manually opened or closed using actuators 22a-22d, respectively, to allow the user to adjust the tension in the tapes or threads.

The aperture 16 extends longitudinally along the axis of artery 61. The site 60 is preferably located in the plane of the upper surface of base 12. The tapes 70, 72 exert a compressive force on the artery 61 which is pressed against a bottom surface 40 as seen in Figure 4. More particularly, the tapes 70, 72 extend in a direction that is substantially perpendicular to the artery 61 axis exposed in the aperture 16. The aperture can have a first pair of lateral sections 18a and 18b which are aligned to accommodate the positioning of tape 70 and the aperture can

also have a second pair of lateral sections 18c and 18d to accommodate the positioning of tape 72. Alternatively, holes extending through the base 12 that are separated from the aperture can be used. The holes are large enough to provide easy feed through and can be angled towards the bottom center to provide compression of the artery at lower tension of the cord.

The size of the aperture can be in the range of 1-3cm in length and 5-15mm in width. The aperture can be narrower in the center and wider at the opposite ends to accommodate the openings or sections 18a-18d.

Between each pair of sections 18a-18b and 18c-18d, a sidewall section of the aperture, namely tabs 24, 26 extend on opposite ends of aperture 16. The tapes 70, 72 compress respective portions of artery 61 on opposite sides of site 60 against tabs 26, 24. As seen in Figure 4, those portions 42, 44 of the bottom surface 40 are in contact with artery 61 and compress it. The bottom surface that surrounds the artery and is in contact with the heart wall can be roughened or abraded to frictionally engage the heart wall around the artery and thereby locally restrict heart motion around the surgical site.

In a preferred embodiment of the invention opposite ends 82 and 84 can be positioned under adjacent ribs 54 and 58, respectively. This eliminates any substantial movement of the base 12 while the heart is pumping so that anastomosis 80 of the end 65 onto site 60 can be quickly completed. The opposite ends 82, 84 can be slightly raised relative to the plane of the remainder of the base 12 to

provide a concave structure to enhance the frictional engagement of sections 82, 84 to ribs 54, 58, respectively. The platform has a substantially rectangular shape with each side having a length in the range between 3.5 cm and 6 cm. Thus the surface area of the platform is between 12cm^2 and 25cm^2, preferably between 14cm^2 and 20cm^2. This size fits readily in the incision between the ribs and can be positioned with both ends extending under the 3rd and 5th ribs. This structure exerts little downward force on the heart or upward force on the artery while immobilizing the artery at the surgical site. Also the anterior-posterior compression of the artery avoids trauma to the artery due to circumferential compression. By engaging the ribs, the retractor is self retaining providing for easier use and manipulation.

As seen in Figure 5, the tape 76 under the bottom surface 94 of the tab 24 lifts the artery 60 to form an occlusion 86. This view also shows the optional channel 92 extending around the periphery of base 12 that is used to irrigate or suction around the site.

The fastening mechanism is illustrated in the partial cross-sectional views of Figures 6A and 6B. The closed position 110 is illustrated in Figure 6A where spring 112 has expanded to move slot 116 in element 115 out of alignment with slot 114 in the outer tube. The cord 72 is displaced and frictionally grasped by the sliding movement of element 115. The user can manually displace 118 to align slot 114 with slot 116 while compressing spring 112. In the "open" position 120, the cord 72 can be easily

removed or pulled through to increase tension.

After the procedure is complete the retractor 10 needs to be removed from the site. In the embodiment of Figure 1, the base 12 can be formed with two sections or plates 14a, 14b. As seen in Figure 7, these components can be separated at joint 25 to allow removal of the retractor 10. The two halves 14a, 14b can be connected with a frictional tube section 96.

In the preferred embodiment illustrated in Figure 8, the retractor 100 can have a plurality of handle attachment sites 102, 104, 106, 108 so that the user can attach the handle 105 at any site to provide the most convenient access to the aperture and facilitate immobilization of other arteries. The handle can alternatively be positioned between the two cords at an orthogonal angle relative to the aperture axis and extending above the top surface of the base.

In another preferred embodiment of the invention illustrated in the perspective view of Figure 9, a retractor 140 has a handle 142, slots 144 located in the plane of the aperture 160 to secure the cords, end sections 162, 164 that engage the ribs 54, 58, tabs 148, 150 for compression of both sides of the artery at the site 60 and a side opening 146 so that the retractor can be removed.

In this embodiment, the LIMA slides out through opening 146 during removal of the retractor after completion of the procedure. This unitary retractor structure 140 can also include various features described previously in connection with the embodiment of Figure 1

including the attached or integrated suction tube, the detachable handle, the irrigation or suction channel with ports or the mechanically actuated fasteners.

A preferred method of stabilizing tissue during a coronary bypass procedure 200 is illustrated in the process flow sequence of Figure 10. A 5-8 cm sized incision is made over the 4th rib and a section of the 4th costal cartilage is removed 202. The LIMA is dissected from the chest wall 204 and divided distally. After blood flow assessment the LIMA can be temporarily closed with a spring loaded clip.

A self-retaining wound retractor is used to distract the edges of the incision and a "trap door" incision is made in the pericardium and the cut edge sewn to the skin to pull the pericardial sack and heart anteriorly. The LAD is exposed and a site suitable for anastomosis is selected for grafting 206. Tapes are inserted in the myocardium with blunt needles approximately 1-2 cm apart 208 and the retractor is inserted 210 with the tapes being pulled through the aperture and positioned in the lateral sections thereof. The tapes are connected to the holder 212 to compress the artery 214 and occlude blood flow on both sides of the grafting site. The tension in the tapes can optionally be adjusted during the procedure to minimize blood loss at the site.

The retractor is secured 216 at the site by positioning one or both ends under adjoining ribs, or alternatively, attaching the handle or arm to the wound retractor or other implement. The grafting site undergoes

less than 0.1 mm of movement in any direction during this example procedure.

The site is suctioned or irrigated 218 during anastomosis, the grafting site is inspected, the tapes are released from the holders, and the retractor is removed either by sliding the LIMA through a side opening in the retractor or detaching a section of the retractor to accommodate removal of the LIMA from the aperture. After blood flow is restored, the site is inspected and closed 220.

Although the use of the retractor has been described in connection with a particular bypass procedure, it can also be used in other procedures such as bypass operations involving the diagonal, right or other coronary artery where movement at the site can interfere with the procedure.

Alternative embodiments involve opening of the chest and positioning the retractor at any exposed site on the heart wall or surrounding areas to immobilize the operative site. The retractor serves to isolate the site and limits or stops motion at the site due to respiratory movement of the lungs or the pumping motion of the heart.

In another preferred embodiment, a stabilizer system or frame 240 manufactured by Genzyme Surgical Products is illustrated in Figure 11 to support a surgical retractor 260 in accordance with the invention.

The frame 240 used with the invention includes a bar 242 having an arm 244 extending orthogonally from a first end and attached to a second arm 246 with a thumb screw at

a second end. Each arm 244, 246 has a pair of mounting elements 252, 255 on which a pivot rod 256 can be mounted. This rod 256 can be rotated 360 degrees to any desired position such that mounting arm 245 can oriented relative to the surgical site as needed to position the retractor 260. Each arm 244, 246 has a pair of grippers 248, 250 that engage anatomical features such as neighboring ribs at the site to stabilize the frame 240.

The mounting arm 245 supports the handle or support arm 262 with a friction fitting 258 which the user tightens with knob 268 to grip arm 262 at region 266. The support arm 262 has a knob 264 at one end that can be turned by the user to engage a post 276 shown in Figure 12A. A ball on the post 276 can be slipped through an opening 265 in the second end of arm 262 and locked into position using knob 264.

The post 276 can be pivoted relative to arm 262 by loosening the knob 264, thus allowing the user to orient the retractor 260 at the site for fine positioning. The post 276 is mounted on a plastic retaining element 270 in this embodiment. The element 270 can be a transparent or opaque molded device that can be separated into two components 272, 274 as described previously. The two components can be attached by friction fit rods 294 that are inserted into holes in element 272. Element 270 can be made with a transparent material to enhance visability at the site.

Both components have raised holder elements 284, 286. Element 284 has a pair of slots 288, 289 that each

frictionally grip an end of a cord which extends through the aperture 278 to attach tissue to the retractor. The second end of each cord is gripped by corresponding slots 290, 292 in element 286.

Tabs or cord retainers 280, 282 are integrally formed with component 274 and function as described previously. In the detailed partial view of Figure 12B, the front inclined surface can be formed at a shallower angle such that the top ridge 279 is narrower. This embodiment of cord retainer 281 affords easier insertion of cords into the aperture.

This embodiment can also be formed with integral suction channels or openings in the top surface of the element 270. A suction tube can be attached through or with the arm 262 or attached to a suction port on element 270.

EQUIVALENTS

While the invention has been described in connection with specific methods and apparatus, it is to be understood by those skilled in the art that the description is by way of example and not as a limitation on the scope of the invention as set forth in the appended claims.

CLAIMS

1. A surgical retractor comprising;

a retaining element having an aperture defining an operative site; and

a holder on the retaining element, the holder positioned to receive a connector that attaches tissue to the retaining element.

2. The surgical retractor of Claim 1 wherein the retaining element comprises a planar section surrounding the aperture.

3. The surgical retractor of Claim 1 further comprising a handle attached to the retaining element.

4. The surgical retractor of Claim 1 further comprising an irrigation channel in the retaining element.

5. The surgical retractor of Claim 1 wherein the aperture comprises a longitudinal section, a first lateral section and a second lateral section.

6. The surgical retractor of Claim 5 wherein the connector comprises a first cord, the first cord extending through the first lateral section, and a second cord extending through the second lateral section.

7. The surgical retractor of Claim 6 wherein the cord comprises flexible tape or thread.

8. The surgical retractor of Claim 1 wherein the retaining element comprises a compression surface that compresses an artery to control blood flow in the artery.

9. The surgical retractor of Claim 9 wherein the compression surface comprises a tab defining an aperture sidewall.

10. The surgical retractor of Claim 9 wherein the connector extends through a first section of the aperture and a second section of the aperture such that the tab is positioned between the first section and the second section.

11. The surgical retractor of Claim 1 further comprising a suction tube attached to the retractor.

12. The surgical retractor of Claim 1 wherein the holder comprises an opening that receives a portion of the connector.

13. The surgical retractor of Claim 12 wherein the holder further comprises a second opening that receives a second portion of the connector.

14. The surgical retractor of Claim 1 wherein the holder comprises a manually actuated fastener.

15. The surgical retractor of Claim 1 wherein the retaining element comprises a plurality of separable sections.

16. The surgical retractor of Claim 1 wherein the retaining element comprises a side opening in a base section extending into the aperture.

17. The surgical retractor of Claim 4 further comprising a plurality of fluid openings in fluid communication with the channel.

18. A method of positioning a surgical site during surgery comprising the steps of:

positioning a retaining element at a surgical site, the retaining element having an aperture that exposes the surgical site; and

connecting tissue at the surgical site to the retaining element with a connector.

19. The method of Claim 18 wherein the connecting step comprises inserting a flexible cord under the artery and connecting the cord to a holder on the retaining element.

20. The method of Claim 18 further comprising positioning a surface of the retaining element against an interior surface of a rib.

21. The method of Claim 18 further comprising the step of suctioning fluid from the surgical site with a suction tube attached to the retaining element.

22. The method of Claim 18 wherein the connecting step further comprises attaching a cord extending through the tissue to a holder on the retaining element.

23. The method of Claim 18 further comprising providing a retaining element having a first plate and a second plate and removing the retaining element from the surgical site by separating the first plate from the second plate.

24. The method of Claim 18 further comprising occluding an artery at the surgical site by pressing the artery against the retaining element.

25. A surgical retractor for a coronary bypass procedure comprising;

a retaining base having an aperture that exposes an operative site;

a holder on the retaining base; and

a cord that attaches to the holder such that artery tissue can be held stationary relative to the

retaining base with the cord.

26. The surgical retractor of Claim 25 wherein the retaining element comprises a planar base section surrounding the aperture.

27. The surgical retractor of Claim 25 further comprising a handle attached to the retaining element.

28. The surgical retractor of Claim 25 further comprising an irrigation channel in the retaining element.

29. The surgical retractor of Claim 25 wherein the aperture comprises a longitudinal section, a first lateral section and a second lateral section.

30. The surgical retractor of Claim 29 wherein the cord comprises a first cord, the first cord extending through the first lateral section, and a second cord extending through the section lateral section.

31. The surgical retractor of Claim 25 wherein the cord comprises flexible tape or thread.

32. The surgical retractor of Claim 25 wherein the retaining element comprises a compression surface that compresses an artery to control blood flow in the artery.

33. The surgical retractor of Claim 25 wherein the compression surface comprises a tab defining an aperture sidewall.

34. The surgical retractor of Claim 33 wherein the connector extends through a first section of the aperture and a second section of the aperture such that the tab is positioned between the first section and the second section.

35. The surgical retractor of Claim 25 further comprising a suction tube attached to the retractor.

36. The surgical retractor of Claim 25 wherein the holder further comprises openings that receive sections of the cord.

37. A method of positioning a coronary artery during bypass surgery comprising the steps of:

positioning a retaining base at a surgical site, the retaining base having an aperture that exposes the coronary artery at the surgical site; and

connecting the coronary artery at the surgical site to the retaining base with a cord; and

grafting a second artery onto the exposed coronary artery positioned in the aperture.

38. The method of Claim 37 wherein the connecting step comprises threading a flexible cord under the artery

and connecting the cord to a holder on the retaining base, the hold comprising a manually actuated fastener.

39. The method of Claim 37 further comprising occluding blood flow in the coronary artery by compressing the artery against the retaining base.

40. The method of Claim 37 further including providing a cord comprising a tape or thread connected at two sections to the retaining base on opposite sides of the retainer.

41. A surgical retractor for a coronary bypass procedure comprising;

a retaining base having an aperture that exposes an operative site, the aperture extending along a longitudinal axis of the base;

a plurality of holders on the retaining base such that a first holder is positioned on a first side of the aperture and a second holder is positioned on a second side of the aperture; and

an arm attached to the base and extending above the base such that a user can position the base at the operative site with a coronary artery exposed through the aperture.

42. The surgical retractor of Claim 41 wherein the retaining element comprises a planar base section surrounding the aperture.

43. The surgical retractor of Claim 41 further comprising an irrigation channel in the retaining element.

44. The surgical retractor of Claim 41 wherein the aperture comprises a longitudinal section, a first lateral section and a second lateral section.

45. The surgical retractor of Claim 44 wherein the cord comprises a first cord, the first cord extending through the first lateral section, and a second cord extending through the section lateral section.

46. The surgical retractor of Claim 41 further comprising a cord held by the first holder and the second holder such that the cord extends through the base around a coronary artery.

47. The surgical retractor of Claim 41 wherein the retaining element comprises a compression surface that compresses an artery to control blood flow in the artery.

48. The surgical retractor of Claim 41 wherein the compression surface comprises a tab defining an aperture sidewall.

49. The surgical retractor of Claim 48 wherein a cord extends between the holders through a first section of the aperture and a second section of the aperture such that the tab is positioned between the first section and the second section.

50. The surgical retractor of Claim 41 further comprising a suction tube attached to the retractor.

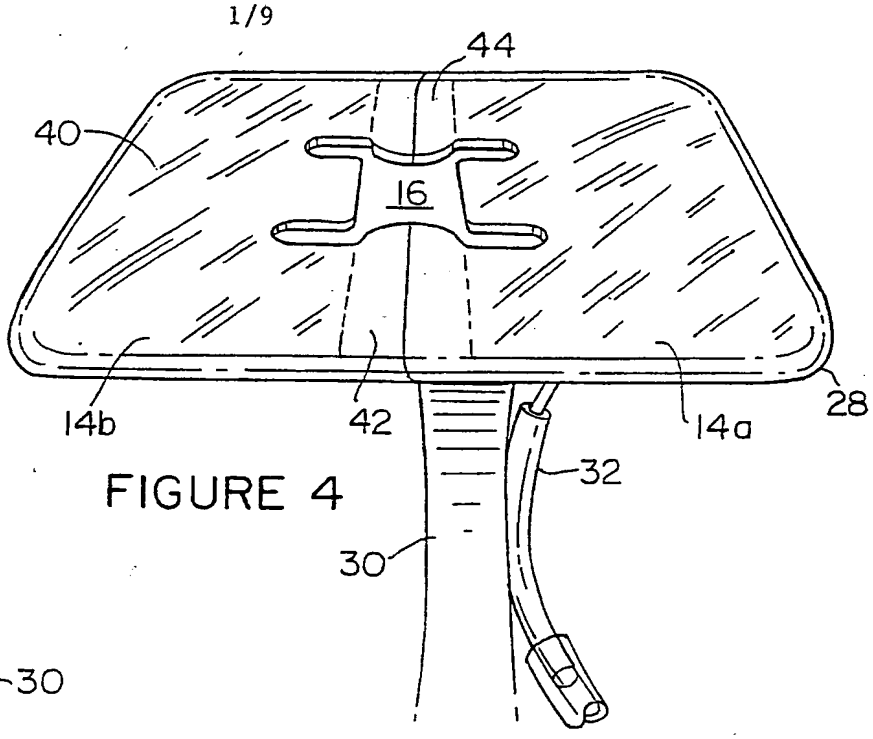

FIGURE 4

FIGURE 1

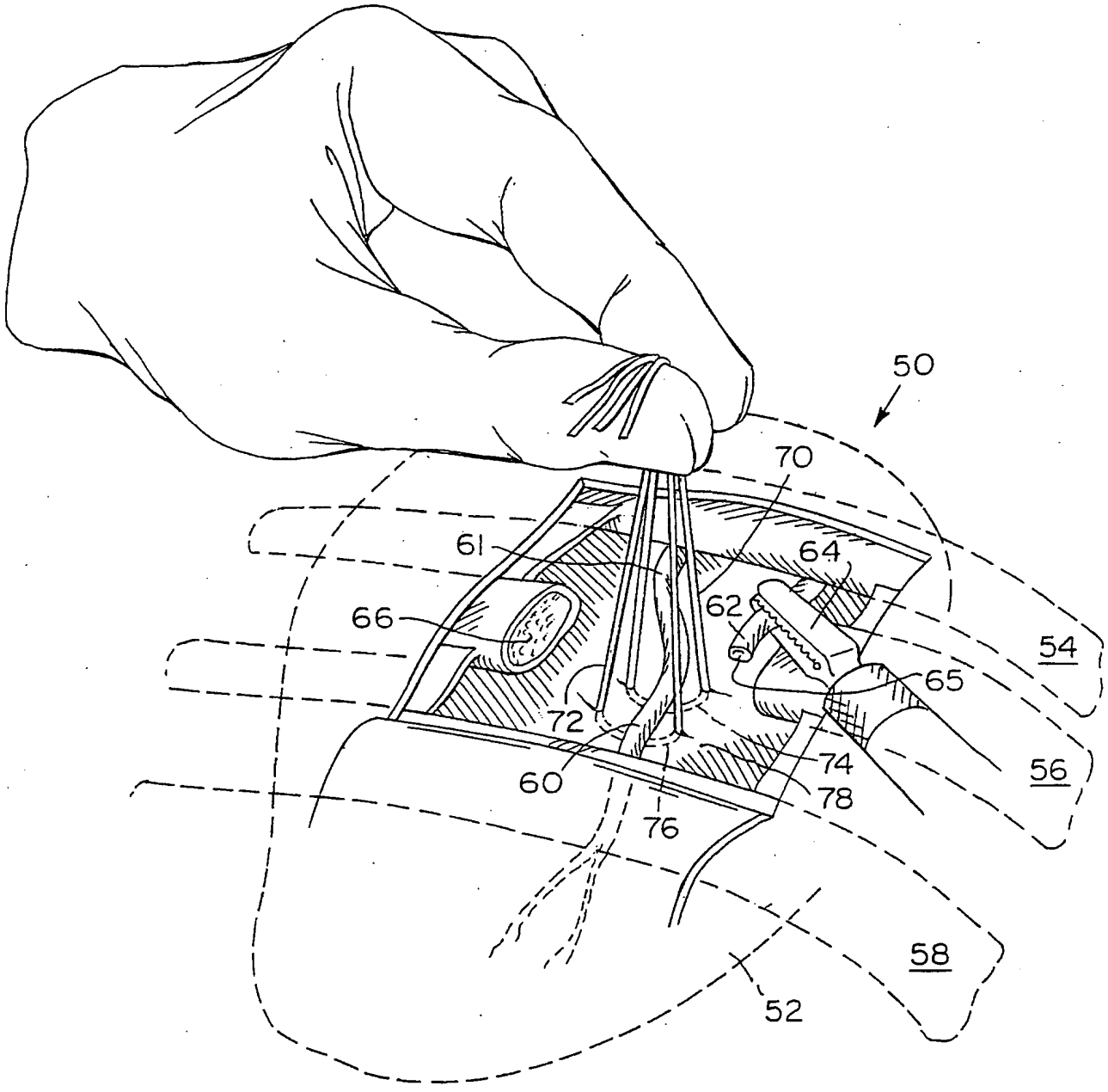

FIGURE 2

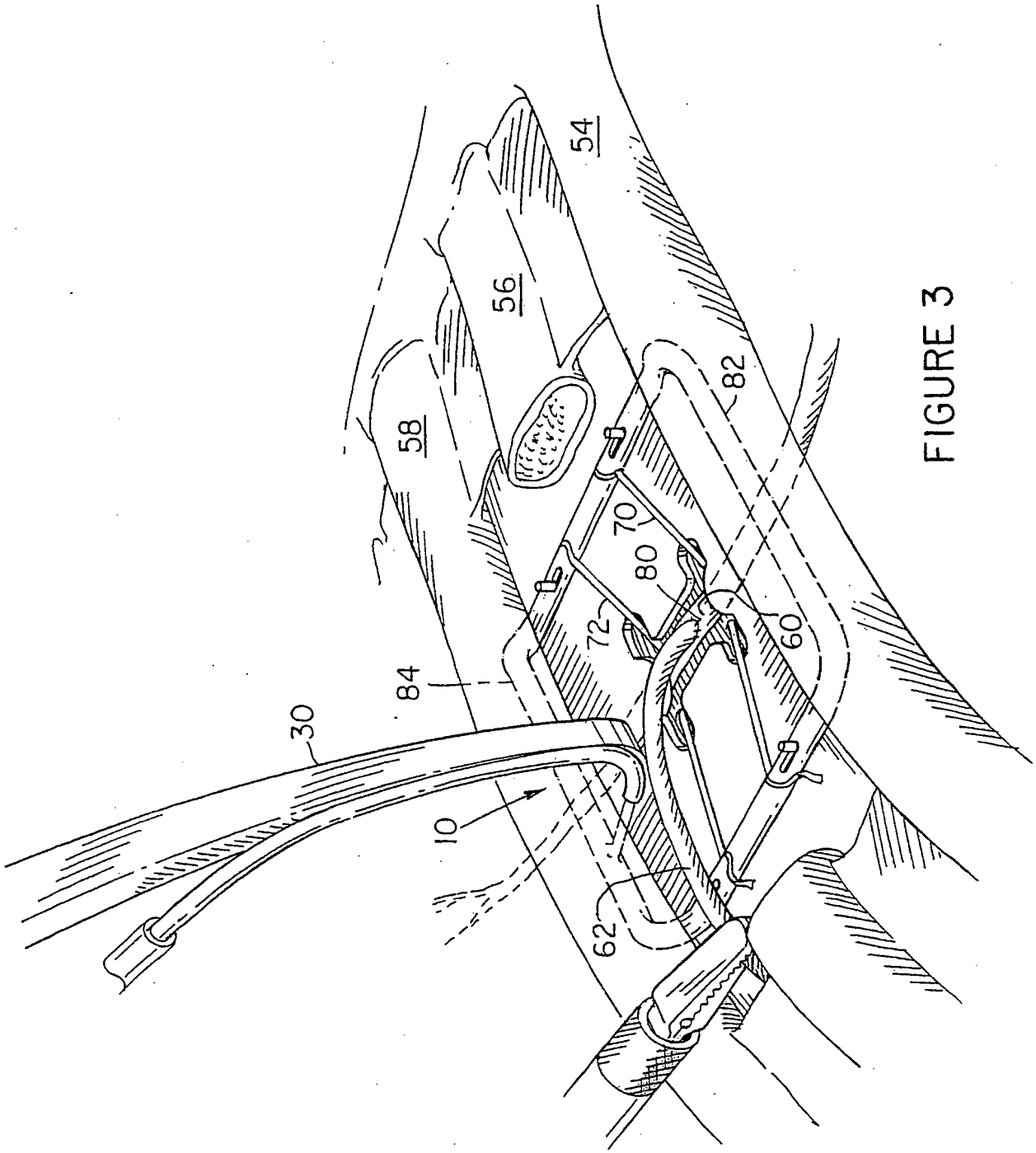

FIGURE 3

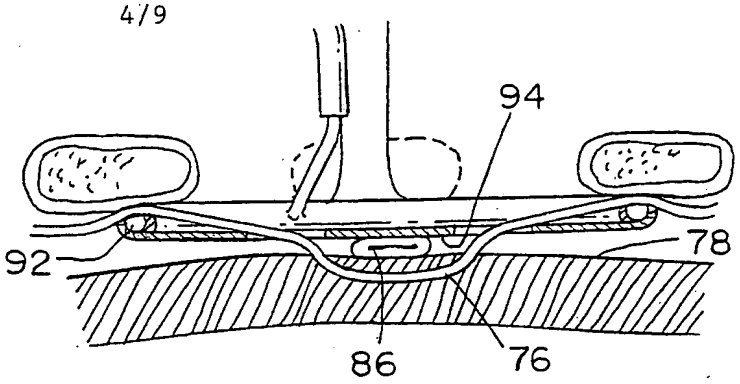

FIGURE 5

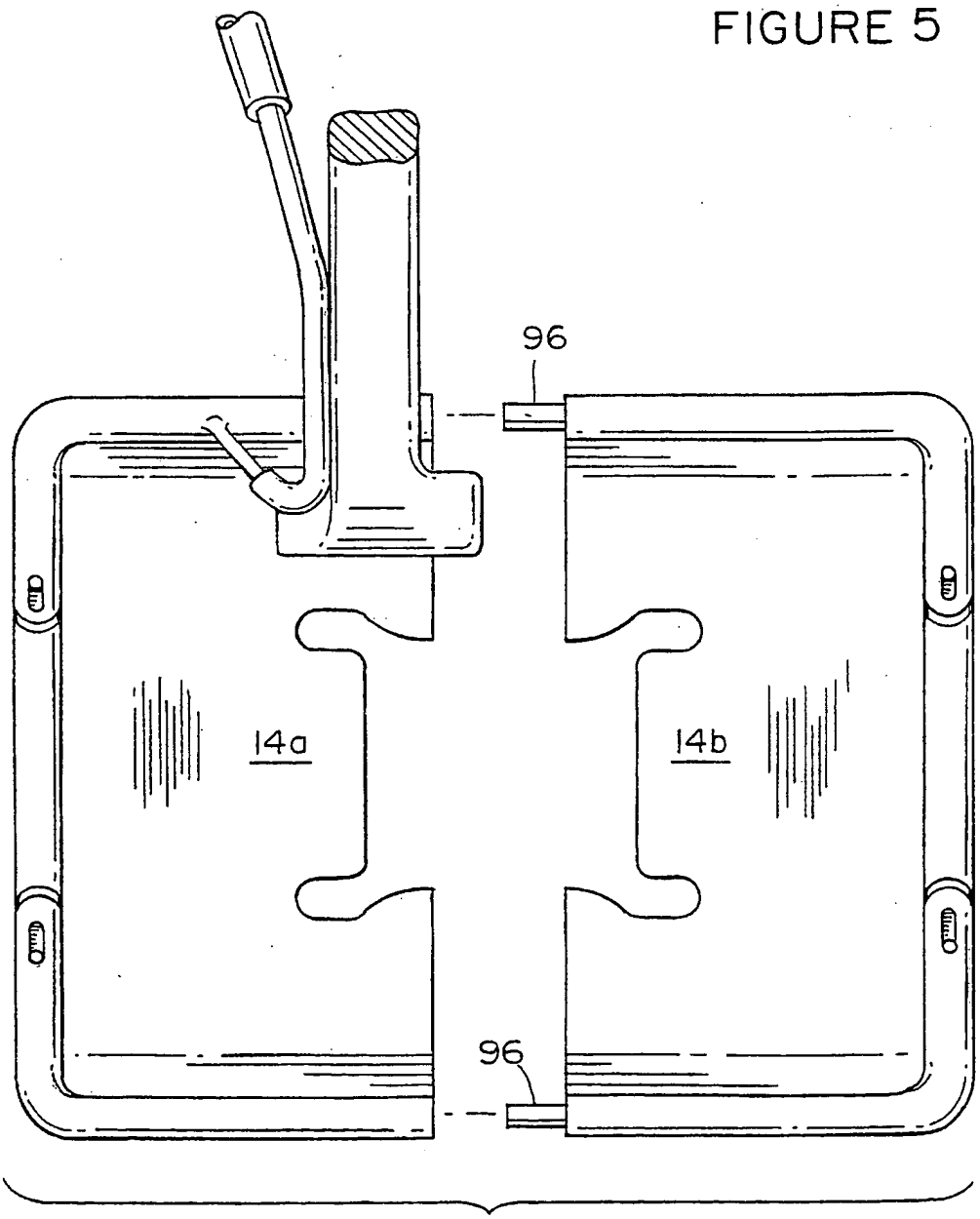

FIGURE 7

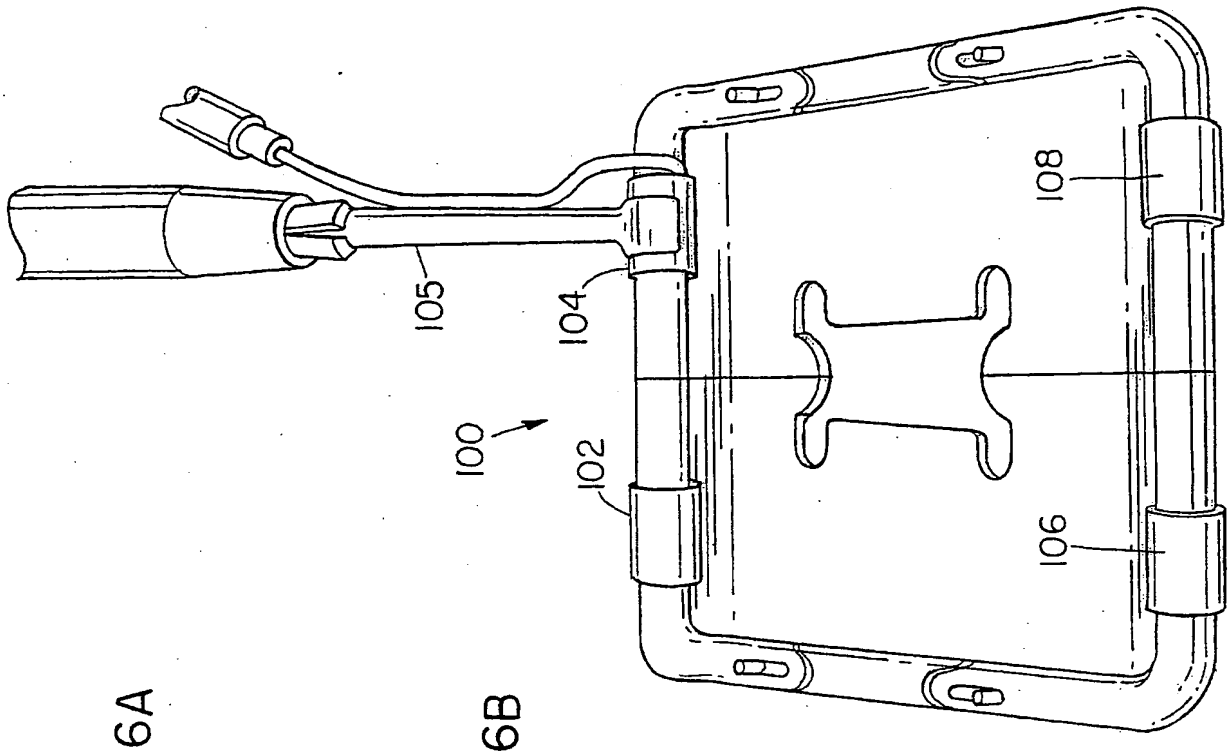

FIGURE 8

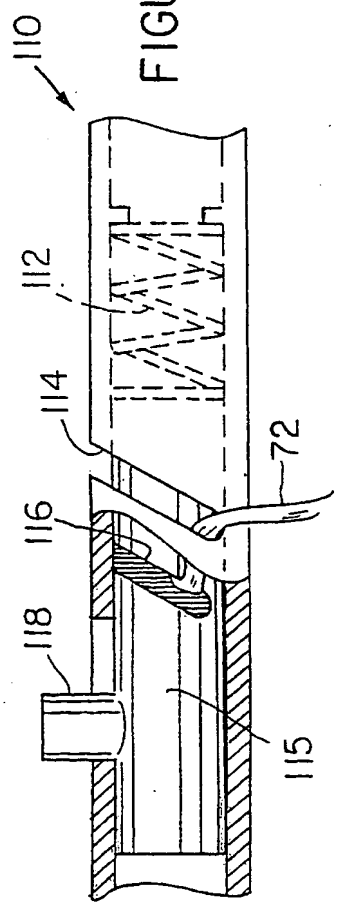

FIGURE 6A

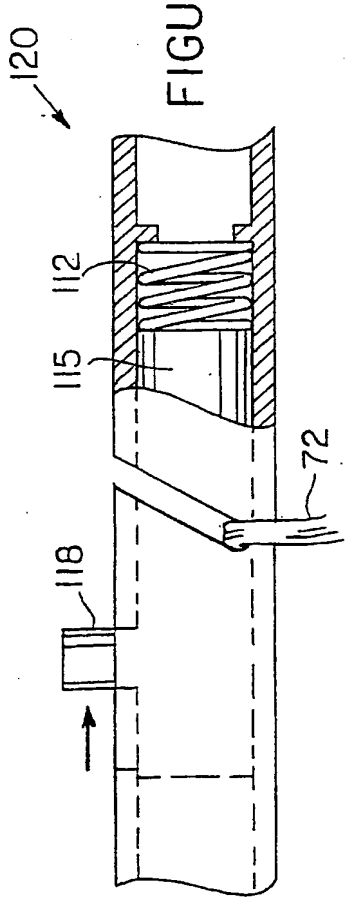

FIGURE 6B

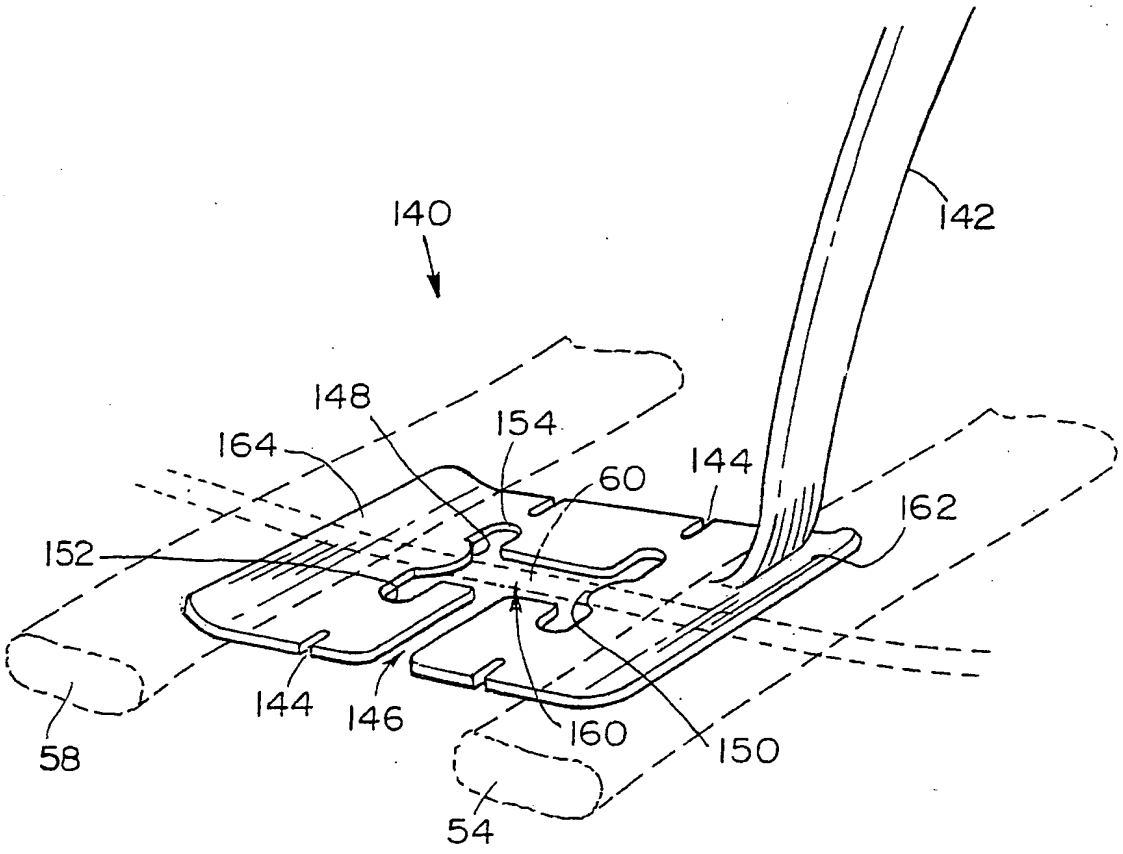

FIGURE 9

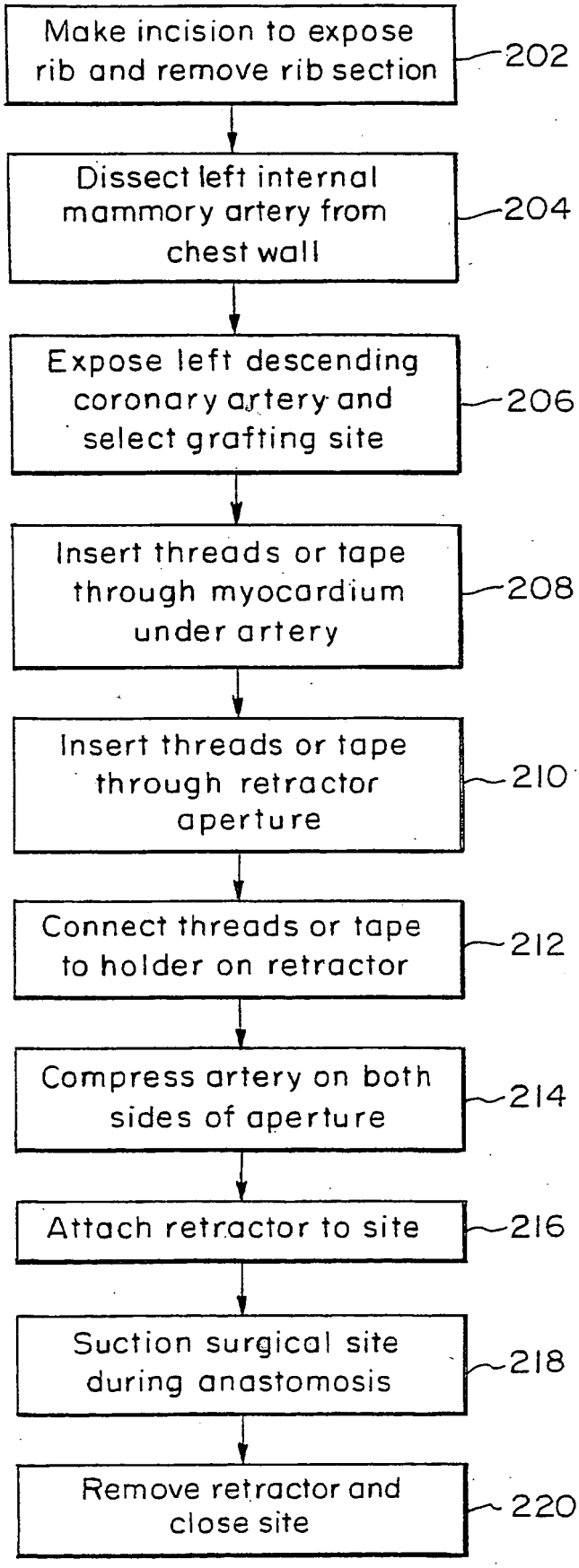

FIGURE 10

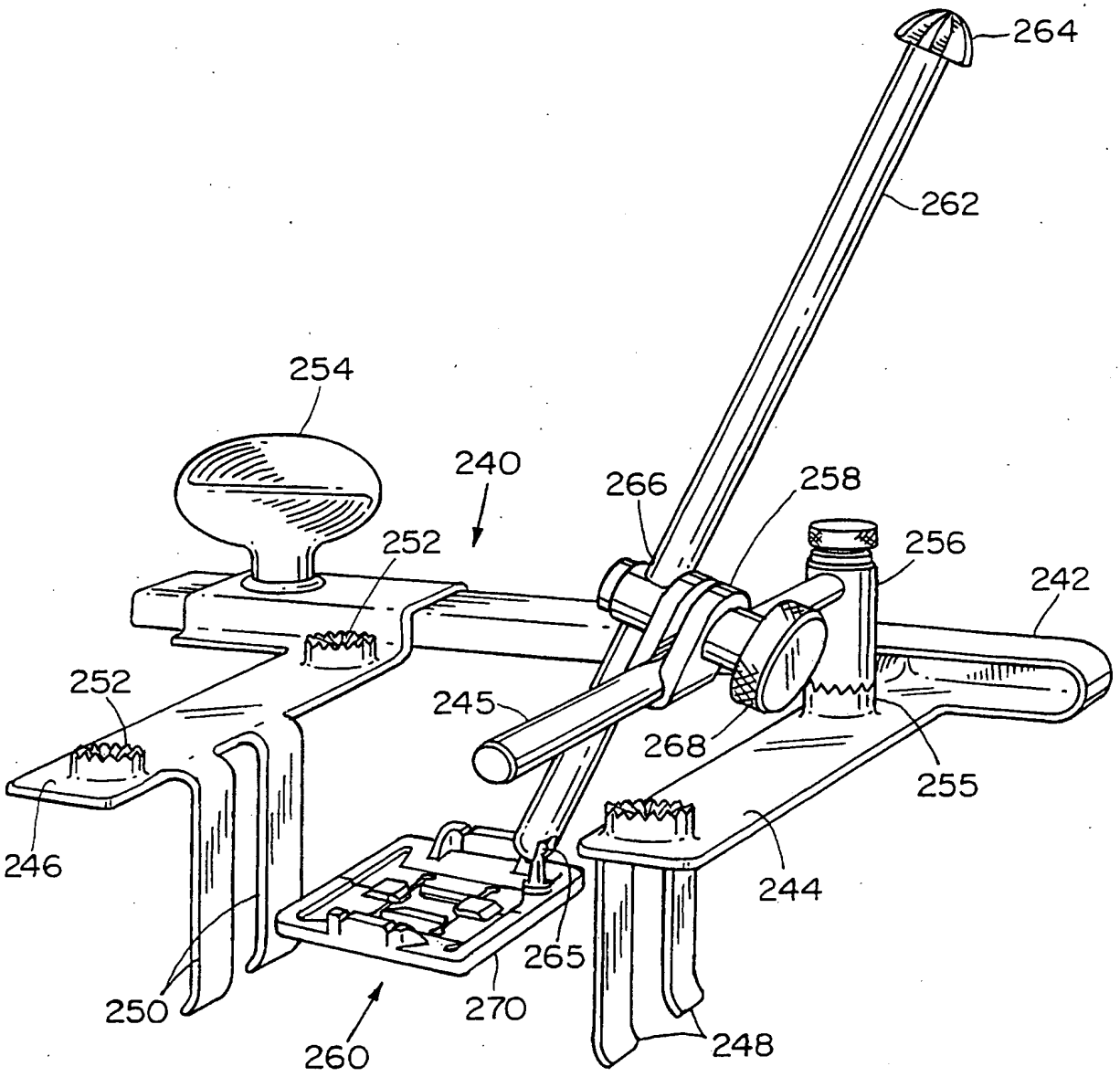

FIGURE 11

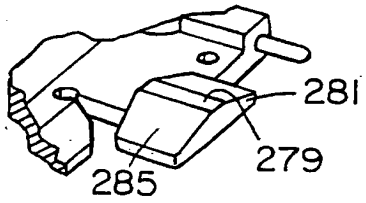

FIGURE 12B

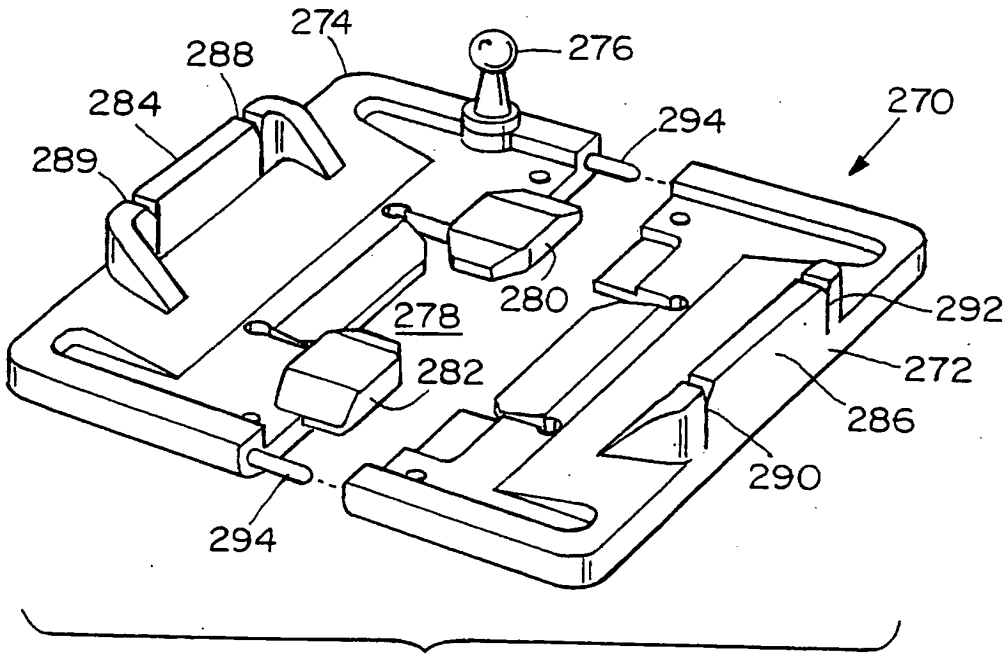

FIGURE 12A

INTERNATIONAL SEARCH REPORT

Internati Application No
PCT/US 98/08348

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 10753 A (MEDTRONIC INC ;BORST CORNELIUS (NL); MANSVELT BECK HENDRICUS J (NL) 27 March 1997 see page 12, line 27 - page 13, line 17; figures 13,14 ---	1
P,X	EP 0 791 330 A (CARDIOTHORACIC SYSTEMS INC) 27 August 1997 see column 34, line 33 - line 59; figures 7B,9F,26B,35 --- -/--	1-4, 8-13,16, 17, 25-28, 31-36, 41-43, 46-50

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 June 1998	07.07.98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Gérard, B

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interna. .l Application No
PCT/US 98/08348

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	EP 0 820 721 A (GUIDANT CORP) 28 January 1998 see column 3, line 23 - line 46	1,25,31, 32,36, 41,46,47
P,X	DE 297 07 567 U (RIESS ANDREAS G) 3 July 1997 see page 6, last paragraph - page 7, paragraph 1; figures 9,13,14	1-3,8, 12-16, 25-27, 31,32, 36,41, 42,46,47

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INTERNATIONAL SEARCH REPORT

Inter nal application No.
PCT/US 98/08348

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18-24,37-40
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati Application No
PCT/US 98/08348

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9710753 A	27-03-1997	AU 7241496 A	09-04-1997
EP 0791330 A	27-08-1997	AU 1480597 A	28-08-1997
		CA 2197614 A	21-08-1997
		JP 10005230 A	13-01-1998
		NO 970753 A	21-08-1997
EP 0820721 A	28-01-1998	NONE	
DE 29707567 U	03-07-1997	NONE	